Baxter

Preventive Maintenance

SIGMA SPECTRUM INFUSION PUMP WITH MASTER DRUG LIBRARY

35700BAX

Pump Operating Software Version 6.02 and 6.05

For use with Master Drug Library Version 6

41394 Rev. A
July 2017

711 Park Avenue
Medina, New York 14103

T 800.356.3454
F 888.894.7794

www.sigmapumps.com

PREVENTIVE MAINTENANCE

Read each PM test completely prior to performing.

To ensure that the SIGMA Spectrum Infusion System is operating within specified parameters, perform the PM tests in this section according to the maintenance schedule below.

After each operation in this procedure, record the results on a copy of the “Preventive Maintenance Check Sheet” on page 20.

NOTE: SIGMA Spectrum Technical Training is available, but not required, for performing Pump PM. Contact MedinaTechTraining@baxter.com for more information.

Preventive Maintenance and Frequency

PM consists of:

- Scheduled inspections, testing, and performance evaluations
- Servicing any SIGMA Spectrum Infusion Pump that fails any inspection, test, or performance evaluation

PM is required on:

- All Pumps in service (use)
- Any Pump suspected of being physically damaged, dropped, or having fluid intrusion.

Recommended PM frequency:

- Pump: Annually

NOTE: A PM or network expiration due date may be entered in the BIOMED options. A “Due for Inspection” reminder will appear at power on followed by the programming screens. At power off, a “Due for Inspection” display will appear prior to Pump shutdown.

When performing an annual PM on SIGMA Spectrum Infusion Systems, record the findings on the check sheet provided. See “Preventive Maintenance Check Sheet” on page 20.

When using the Annual Preventive Maintenance Check Sheet:

- Enter the Hospital/Facility name in the space provided.
- Enter the Biomed name and date of the test.
- Perform the inspections, tests, and performance evaluations described in this chapter.
- Record the test result findings.
- Return any Pump to Baxter that fails any inspection or test.

Pump Identification

Serial Number and Operating Software Version

The Pump's serial number and operating software version are located in two areas, the Power Status screen and the User Options screen.

Record and verify the serial number and software version of the Pump using one of the methods described in this section.

To verify the Pump serial number and software version from the Power Status screen:

1. Press **ON/OFF** to power on the Pump.
2. View the current software version and serial number.
3. Record the software version and serial number on the Preventive Maintenance Check Sheet.
4. Check the label on the bottom of the Pump. Verify the serial number is the same.

To verify the Pump serial number and software version from the User Options menu:

1. Press **ON/OFF** to power on the Pump.
2. From the Select Care Area screen, press the **options menu** soft key (software version 6.05) or **Help** then the **Options** soft Key (software version 6.02).
3. Select **User Options** and press **OK**.
4. Select **View Information** and press **OK**.
5. Select **Pump Information** and press **OK** to display the Pump Info screen.
6. Record the software version and serial number on the Preventive Maintenance Check Sheet.
7. Check the label on the bottom of the Pump. Verify the serial number is the same.
8. Press the **exit** soft key four times to return to the Care Area screen.

Network Connectivity

To verify current Network connectivity:

1. From the Select Care Area screen, press the **options menu** soft key (software version 6.05) or **Help** then the **Options** soft Key (software version 6.02).

2. Select **Biomed Options** and press **OK**.
3. Enter the Biomed password and press **OK**.
4. Select **Network Configuration** and press **OK**.
5. Select **Network Status** and press **OK**.

   When using a WBM, a wireless icon (in the top right corner of the Pump display) will indicate the status of the network connection. See the “Pump Icons” section of the device’s Operator’s manual.
6. Record the status on the Preventive Maintenance Check Sheet.

Active Drug Library

If using a WBM, the Drug Library will load automatically from the Gateway Server once the Network Configuration is complete.

NOTE: It may take several minutes for the Drug Library BDL file to begin downloading to the Pump.

The message, “Activating new drug library” appears with a progress bar on the Pump’s display.

To confirm Drug Library activation:

» When the new Drug Library has been activated on the Pump, the screen will display “COMPLETE”. Press **OK** to confirm activation.

NOTE: If the Drug Library is not current or is missing, see “Programming the Pump” in the device’s Operator’s Manual.

WARNING **Confirm Drug Library.**

- Master Drug Library Administrators (MDLAs) should verify the correct Drug Library is installed when deploying the Drug Library to Pumps.
- Master Drug Library Administrators (MDLAs) should verify the Drug Library transfer is successful after deployment.
- Users should verify the correct Drug Library is installed on the deployed Pumps.
- Before implementation, clinical users at each facility must thoroughly test and validate their Drug Library per their facility’s procedure to ensure configuration and workflow reflect clinical practice.

To identify the Active Drug Library:

The name and version of the Pump’s active Drug Library BDL file can be viewed on two screens of the Pump’s display: the Power Status screen and the User Options screen.

Record and verify the Pump’s active Drug Library BDL file using one of the following methods.

The Power Status screen (the Pump must be powered off):

1. Press **ON/OFF** to power on the Pump and view the current software version and serial number.
2. Record the Pump's active Drug Library BDL file on the Preventive Maintenance Check Sheet.
3. Verify the current Drug Library BDL file in use with the facility's pharmacy or MDLA.
4. Record the facility's current Drug Library BDL file on the Preventive Maintenance Check Sheet and verify they are the same.
5. Press **ON/OFF** to power off the Pump.

NOTE: The User Options screen (the Pump must be powered off):

1. Press **ON/OFF** to power on the Pump and view the current software version and serial number.
2. From the Select Care Area screen, press the **options menu** soft key (software version 6.05) or **Help** then the **Options** soft Key (software version 6.02).
3. Select **User Options** and press **OK**.
4. Select **View Information** and press **OK**.
5. Select **Library Information** and press **OK**.
6. Record the Pump's active Drug Library BDL file and date on the Preventive Maintenance Check Sheet.
7. Verify the current Drug Library BDL file in use with the facility's pharmacy or MDLA.
8. Record the facility's current Drug Library BDL file on the Preventive Maintenance Check Sheet.
9. Press **ON/OFF** to power off the Pump.

Visual Inspection

To inspect the Pump:

1. Inspect the Pump for visual evidence of damage and/or defects to exterior components such as dents, cracks, cuts, heat damage or fluid intrusion.

- Pump Case
- Pump Display
- Keypad
- Keyhole
- Pump Door
- IV Set Tube Channel
- Pole Clamp
- External Power Adaptor/Accessory Connection port

NOTE: The IV tube channel must be free of foreign materials and dry for both testing and use.

2. Verify presence and legibility of all labels. Replace/order labels as necessary.

   For label location, see Appendix A: “Technical Drawings” in the Service Manual.

   - Company ID label
   - Power/Bolus label
   - Certification label
   - Serial Number label
   - Tubing ID label
   - Direction of Flow label
   - Replace/order labels as necessary.
3. Record the findings on the Preventive Maintenance Check Sheet.

Visual Inspection - AC Power Adaptor

To inspect the AC Power Adaptor:

1. Inspect the AC Power Adaptor for visual evidence of damage and/or defects such as cracks, bent prongs, cuts or exposed wires or dents.

   - AC Power Adaptor Module
   - AC Power Adaptor Cord
   - AC Power Cord Adaptor Retainer

   If the AC Power Cord Adaptor Retainer is damaged,

   - Remove the Retainer and inspect the 6-pin Plug Connector (on the AC Power Adaptor cord).
   - Inspect the External Power Adaptor/Accessory Connection port (on the back of the Pump) for signs of damage such as cracks or missing pins.

   NOTE: If damage is found on the AC Power Adaptor, it may be sent for service repair (without the Pump).

2. If no signs of damage are found, plug the AC Power Adaptor into a working wall receptacle.

3. Verify that the green LED on the AC Power Adaptor is lit while plugged in and a plug icon appears on the Pump's Charging screen.
4. Verify legibility of all labels on the AC Power Adaptor Module.
5. Record the findings on the Preventive Maintenance Check Sheet.

Preventive Maintenance Pump Tests

WARNING **Flow Rate Inaccuracy.**

Rate accuracy can be affected by variations of fluid viscosity, fluid temperature, head height or back pressure, or any combination thereof. In addition to IV set specific warnings, the following can cause flow rate inaccuracies and must be avoided:

- Incompatible brand IV sets and compatible brand IV sets with unusually large or small diameters or unusually stiff materials.
- Using a dropped, damaged, dirty or wet Pump.
- Pressurizing IV bags.
- Non-vented IV sets with rigid non-vented containers.
- Vents on sets or burettes left in the closed position when they should be open.
- Using Minidrip chambers for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause air in line or upstream occlusion alarms.
- Laying the IV container flat. Doing so may influence flow rate accuracy and cause upstream occlusion and air in line alarms.
- Exceeding 500 mL/hr flow rate settings when using sets with backcheck valves. Doing so may influence flow rate accuracy or cause air in line or upstream occlusion alarms.
- Flow rates above 300 mL/hr may cause fluid to be siphoned from the primary container during a secondary infusion. For information on secondary infusions, refer to the device's Operator's manual.

NOTE: Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

WARNING **Use the Specified Manufacturer's IV Set.**

A label located on the top of the Pump indicates the specific type of IV tubing that the Pump has been calibrated for. The use of other manufacturers' brands or type tubing could produce Pump inaccuracies that could be unsafe for patients.

WARNING **Do Not Reuse Tubing.**

Do not reload pumped-on tubing (the tubing segment previously used in the pumping channel) into the pumping channel. Doing so will cause alarms and adversely affect flow rate accuracy.

CAUTION **Perform Preventive Maintenance Annually.**

Pumps should be tested for proper performance annually and also whenever damage from drops, fluid intrusion and other causes is suspected.

CAUTION **Avoid Bright Natural Sunlight or Artificial Overhead Light.**

Bright Light (equivalent to greater than or equal to 100 watt incandescent bulb) within 30.5 cm (1 ft) above the Pump's keyhole (load point #1) may affect the Pump's ability to recognize the IV set slide clamp during set loading. To prevent alarms or continuous system errors:

- Increase the distance between the Pump and the light source.
- Move the Pump to an adjacent location.

CAUTION **Avoid Overheating.**

When operating the Pump, keep out of bright sunlight or direct heat sources to prevent overheating.

Equipment Required

- SIGMA Spectrum Infusion System
- IV set compatible with the Pump being tested (must not include a backcheck valve)
  - Recommended test set: Preventive Maintenance (PM) Kit P/N 42059, (1 each P/N 99004 Alternate Test Set, 10 each P/N 99051-1 38 cm (15 in) segment.
- 3-way valve (P/N 55568)
- IV container (250mL minimum or 1000 mL recommended) to be used as pumping source.
- Balance or scale with a minimum resolution of 0.1 g calibrated to a range of 0 to 100 g (used for gravimetric flow rate accuracy test).
- A 25 mL class "A" graduated collection vessel (used for volumetric flow rate accuracy test). Volumetric vessel should be TC (to contain) with a resolution of 0.2 mL.
- Pressure gauge with at least 207 kPa (30 psi) accuracy of 0.5%
- IV Pole or test fixture
- One hemostat
- Saline, Deionized Water (ISO class III) or distilled water
- Collection vessel (cup, bag, or equivalent)

NOTE: All measurement tools should be calibrated to National Institute of Standards and Technology (NIST) standards.

NOTE: Do not use tap water.

NOTE: Do not use IV sets that include backcheck valves when performing preventive maintenance tests.

Keypad Operation Test

To check the Pump keypad and display for proper operation:

1. Plug the AC Power Adaptor into a working wall outlet, or install a Battery Module.
2. Press **ON/OFF** to power on the Pump.
3. When the Care Area screen appears, press **SETUP**.
4. Using the keypad, enter the letters **BA** then press **OK**.
5. Press the down arrow soft key to select **BASIC** and press **OK**. The Pump is now in BASIC MODE.
6. Press **OK** to select Primary Bag.
7. Press **OK** to select mL/hr.
8. Press **9**, **0**, and the decimal key on the keypad.
9. Verify that numbers and a decimal point (90**.**) appear in the Rate mL/hr field.
10. Press the **clear rate** soft key.
11. Press **5**, **6, 7, 8** on the keypad.
12. Verify that numbers (5678) appear in the Rate mL/hr field.
13. Press the **clear rate** soft key.
14. Press **1**, **2**, **3**, **4** on the keypad.
15. Verify that numbers (1234) appear in the Rate mL/hr field.
16. Press **RUN/STOP**.

    The message, “Above UPPER Hard Limit Enter a Value of 999 or lower” appears.
17. Press **OK**. The message disappears.
18. Press the **clear program** soft key.

    A “Clear Program? yes/no” prompt appears.
19. Press the **yes** soft key.

    The Care Area Selection screen appears.
20. Press **ON/OFF** to power off the Pump.
21. If the keypad malfunctions, repeat the test.
22. If the error repeats, remove the Pump from service and contact Technical Support for service.
23. Record the findings on the Preventive Maintenance Check Sheet.

Memory Test

To test the Pump's memory:

1. Plug the AC Power Adaptor into a working wall outlet, or install a Battery Module.
2. Press **ON/OFF** to power on the Pump.
3. Select any **Care Area** and press **OK**.

   NOTE: If the "New Patient Yes/No?" prompt appears, press the **yes** soft key.

4. Press **OK** to view the Drug Library.
5. From the Drug Library, select **BASIC** and press **OK**.
6. Select **Primary Bag** and press **OK**.
7. For Mode select **mL/hr** and press **OK**.
8. Set the Rate to **100** mL/hr and press **OK**.
9. Set VTBI mL to **50** mL and press **OK**.
10. Press **ON/OFF** to power off the Pump.
11. Press **ON/OFF** to power on the Pump.
12. On the "New Patient Yes/No?" screen, press the **no** soft key.
13. Verify that the Rate and VTBI parameters were saved. (100 mL / 50 mL)
14. Press **ON/OFF** to power off the Pump.
15. Record the findings on the Preventive Maintenance Check Sheet.

Pump Operation Tests

The Pump operation tests include:

- Downstream (Distal) Occlusion Sensor
- Upstream (Proximal) Occlusion Sensor
- Gravimetric or Volumetric Flow Rate Accuracy
- Air Detection

Test Setup

To prepare the Pump for testing:

NOTE: The IV sets being used for testing the Pump must be compatible with the Pump under test. The proper IV set calibration is listed on the label located on the top of the Pump.

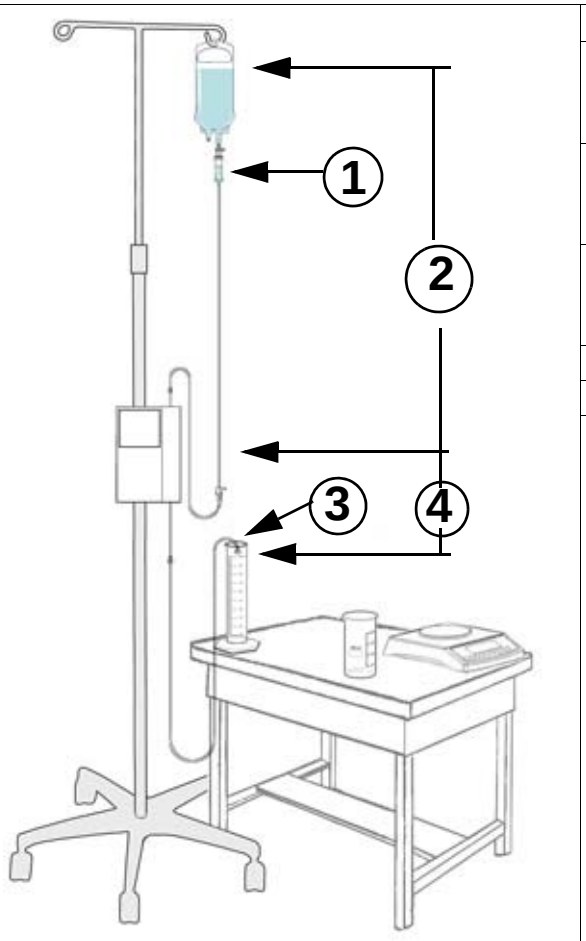
NOTE: Do not use IV sets that include backcheck valves when performing preventive maintenance tests.

NOTE: Do not use IV sets that include mini drip chambers when performing preventive maintenance tests.

NOTE: The IV container needs to be collapsible or vented to the atmosphere.

NOTE: If the Pump is being tested for accuracy following a clinical problem, it is essential to use an IV set of the same catalog number and lot number as that in use when the problem occurred.

1. Attach the pole clamp to a stable IV pole.



1	The drip chamber filled to fill line.
2	610 ± 51 mm (24 in ± 2 in) between the top of the fluid level and the center of the Pump.
3	Do not allow the tip of the IV set to fall below the fluid level of the collection cup or graduated cylinder during the test.
4	The maximum vertical distance of 304.8 mm (12 in) from the center of the pump to the distal end of the IV set

Figure 1. Test Setup.

2. Obtain a new compatible IV set.
3. Connect the set to the IV container.
4. Verify that the IV bag contains enough fluid to complete the testing.
5. Verify the drip chamber is at fill line.
6. Verify that there is no foreign material in the delivery solution during flow rate testing.
7. Prime the IV set, removing all air from the tubing.

   NOTE: Follow the instructions on the IV bag to fill drip chamber.

8. Plug the AC Power Adaptor into a working wall outlet, or install a Battery Module
9. Insert the slide clamp into the keyhole and open the Pump door. Verify that the Pump powers on.

10. Inspect the IV tube channel. Confirm that it is free of foreign materials and dry for both testing and use.
11. Load the IV set into the Pump following the Direction of Flow diagram inside the Pump door, and close the door.

    NOTE: If using the IV test header, load that section into the Pump. Leave 1.2 m (48 ±0.5 in) of tubing between the lower side of the Pump and the end of the IV set.

12. Remove the slide clamp and open the roller clamp.
13. Verify that the tubing above and below the Pump is not occluded.

Downstream (Distal) Occlusion Sensor Test

It is suggested to only use the calibrated IV set for the Downstream Occlusion Sensor Test.

NOTE: Softer tubing between the Pump, air in the gauge, or air in the line can result in inaccurate results.

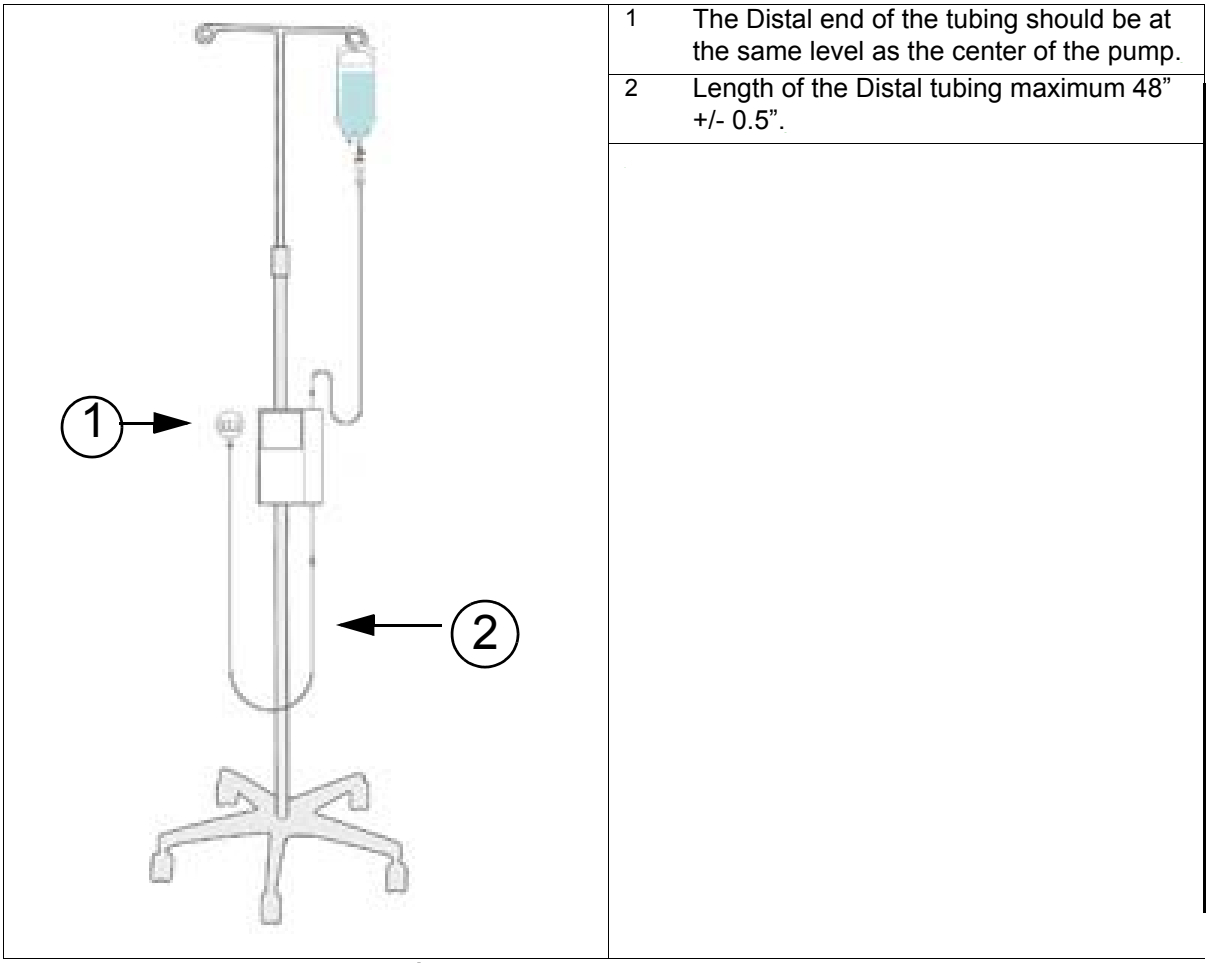
To test the downstream occlusion sensor:

1. Load a primed IV set into the Pump for testing. See “Test Setup.” on page 11.
2. On the Care Area screen, press the **options menu** soft key (software version 6.05) or **Help** then the **Options** soft Key (software version 6.02).
3. On the Options screen, select **User Options** and press **OK**.
4. Select **Alarm Settings** and press **OK**.
5. Advance the highlighted field to **DS Pressure Limit** by pressing **OK** for each field.
6. Press the arrow soft key to set the DS Pressure Limit to **med** (medium) and press **OK**.

   NOTE: The Downstream Occlusion Sensor Test must be performed with the downstream pressure limit setting at medium. Any other setting will cause Pump test failure.

7. Press the **exit** soft key two times to exit User Options.
8. Select **Biomed Options** and press **OK.**
9. Enter the Biomed password and press **OK**.
10. Select **Sensor Configuration** and press **OK**.
11. Verify that the Downstream Occlusion Auto Restart is set to On.
12. Press the **exit** soft key three times to exit the Sensor Configuration screen, Biomed Options screen and Options screen.
13. Select a **Care Area** and press **OK**.
14. Press **OK** to view the Drug Library.
15. Press the arrow soft key to select **BASIC** and press **OK**.

16. Select **Primary Bag** and press **OK**.
17. For Mode select **mL/hr** and press **OK**.
18. Set the Rate to **100** mL/hr and press **OK**.
19. Set the VTBI mL to **50** mL and press **OK**.
20. Attach the 3-way valve P/N 55568 to the pressure gauge.
21. Connect a pressure gauge to the end of a fluid-filled new IV set with approximately 1.2 m (48 ±0.5 in) of tubing between the Pump and gauge. See Figure 2.



1	The Distal end of the tubing should be at the same level as the center of the pump.
2	Length of the Distal tubing maximum 48” +/- 0.5”.

Figure 2. Downstream Pressure Test

NOTE: Verify that the pressure gauge is properly primed and set up per manufacturer’s instructions.

NOTE: Make sure there is no air inside the 3-way valve.

NOTE: Make sure to close the 3-way valve.

NOTE: The pressure gauge should be at the same height as the Pump.

22. Press **RUN/STOP** to start the infusion.

    NOTE: The Pump may indicate BAG NEAR EMPTY <30 MIN REMAIN. Press **OK** to silence this alarm.

    NOTE: If the Pump displays a Check Flow screen, press the **yes** soft key to proceed to the Infusion Running Screen.

23. Verify that the Pump displays a DOWNSTREAM OCCLUSION alarm at a pressure within the 89 kPa ±41 kPa (48 kPa to 131 kPa) [13 psi ±6 psi (7 psi to 19 psi)] occlusion trip pressure setting (check the maximum pressure on gauge).
24. Remove the pressure gauge and confirm that the Pump auto restarts.
25. Press **RUN/STOP** to stop the infusion.

    NOTE: In the event of a test failure, confirm the failure by repeating the test with a new (unused) IV set.

26. Record findings on the Preventive Maintenance Check Sheet.

Upstream (Proximal) Occlusion Sensor Test

NOTE: If the Pump has been inactive for 2 minutes, an Inactivity alarm will sound. Follow the screen prompts to silence the alarm.

To test the upstream occlusion sensor:

1. Load a primed IV set into the Pump for testing. See “Test Setup.” on page 11.
2. Select any **Care Area** and press **OK**.
3. Press **OK** to view the Drug Library.
4. Press the arrow soft key to select **BASIC** and press **OK**.
5. Select **Primary Bag** and press **OK**.
6. For Mode select **mL/hr** and press **OK**.
7. Set the Rate to **100** mL/hr and press **OK**.
8. Set VTBI mL to **13.3** mL and press **OK**.
9. Press the **clear total** soft key to clear the volume given.
10. Occlude IV set 30.2 cm (12 in) above the Pump with a hemostat.
11. Press **RUN/STOP** to start the infusion.

    NOTE: The Pump may indicate BAG NEAR EMPTY <30 MIN REMAIN. Press **OK** to silence this alarm.

NOTE: If the Pump displays a Check Flow screen, press the **yes** soft key to proceed to the Infusion Running Screen.

12. Verify that the Pump indicates an UPSTREAM OCCLUSION alarm prior to the infusion complete message.
13. Release the occlusion by removing the hemostat.
14. Press **OK** to acknowledge the alarm.
15. Press **RUN/STOP** to continue to run the infusion until the IV normalizes (air removed from line) (5-10 seconds).
16. Press **RUN/STOP** to stop the infusion.

    NOTE: In the event of a test failure, confirm failure by repeating the test with a new (unused) IV set.

17. Record the findings on the Preventive Maintenance Check Sheet.

Flow Rate Accuracy Test

Either Volumetric or Gravimetric methods of collection may be used. Begin to test the flow rate accuracy with either method by performing the following steps.

To test the flow rate accuracy:

1. Load a primed IV set into the Pump for testing. See “Test Setup.” on page 11.

   NOTE: If the “New Patient Yes/No?” prompt appears, press the **yes** soft key.

2. Verify that the roller clamp is open.
3. Select any **Care Area** and press **OK**.
4. Press **OK** to view the Drug Library.
5. From the Drug Library, select **BASIC** and then press **OK**.
6. Select **Primary Bag** and press **OK**.
7. For Mode select **mL/hr** and press **OK**.
8. Set the Rate to **40** mL/hr and press **OK**.
9. Set VTBI mL to **20** mL and press **OK**. (The run time is 30 minutes)
10. Set up the collection cup or graduated cylinder.

    NOTE: The collection cup or graduated cylinder should be dry.

11. Press **RUN/STOP**. Allow the infusion to run until the Pump displays an infusion complete alarm.

NOTE: If the Pump displays a Check Flow screen, press the **yes** soft key to proceed to the Infusion Running Screen.

12. At the Infusion Complete Alarm, immediately press **RUN/STOP** to stop the infusion.

NOTE: KVO will continue to run until **RUN/STOP** is pressed. KVO will allow fluid to flow into the collection cup.

Volumetric Test

13. Set the graduated cylinder on a flat surface.
14. Visually measure the fluid in the graduated cylinder from the 40 mL / hr run. Read the level from the bottom of the fluid meniscus. See Figure 3.

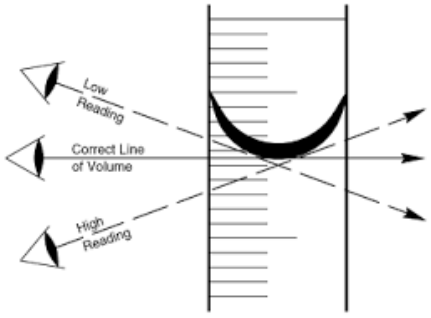


Figure 3. Measuring the fluid level.

15. Record the volume on the Preventive Maintenance Check Sheet.
    - If the test procedure fails, review the test set up to ensure that the process has been followed correctly. Install a new approved IV set and repeat the test.
    - If the error repeats, contact Baxter technical support and service at:
      - Telephone: 800.356.3454 or
      - E-mail: MedinaTechSupport@baxter.com

Gravimetric Test

16. Tare (zero) Scale
17. Weigh (in grams) the fluid in the collection cup *from the 40 mL/hr run*.
18. On the balance, press Tare (zero) while fluid is in the cup.
19. Remove the cup, empty the cup and dry the inside with a lint-free absorbent cloth.
20. Weigh the empty cup. This value multiplied by negative one (-1) is the weight of the fluid collected.
21. Record the weight on the Preventive Maintenance Check Sheet.

- If the test procedure fails, review the test set up to ensure that the process has been followed correctly. Install a new approved IV set and repeat the test.
- If the error repeats, contact Baxter technical support and service at:
  - Telephone: 800.356.3454 or
  - E-mail: MedinaTechSupport@baxter.com

Air Detection Test

NOTE: If the Pump has been inactive for 2 minutes, an Inactivity alarm will sound. Follow the screen prompts to silence the alarm.

To test the air detection:

1. Load a primed IV set into the Pump for testing. See “Test Setup” Figure 1.

   NOTE: If the “New Patient Yes/No?” prompt appears, press the **yes** soft key.

2. Select any **Care Area** and press **OK**.
3. Press **OK** to view the Drug Library.
4. Press the arrow soft key to select **BASIC** and press **OK**.
5. Select **Primary Bag** and press **OK**.
6. For Mode select **mL/hr** and press **OK**.
7. Set the Rate to **100** mL/hr and press **OK**.
8. Set VTBI mL to **50** mL and press **OK**.
9. Press **RUN/STOP** to start the infusion.

   The Check Flow screen appears.
10. Press the **yes** soft key to proceed to the Infusion Running screen.
11. Introduce a 2.5 cm (1 in) minimum air bubble into the IV set upstream from the Pump.

    NOTE: Although there are various methods to introduce a bubble into a line, one option is while the Pump is running, clamp the line using a hemostat above the IV test header (if used). Disconnect the luer lock for approximately 3 seconds and then reconnect. Remove the hemostat.

12. Verify the Pump goes into Air In Line alarm.
13. Close the roller clamp to prevent free flow.
14. Unload the IV set to remove air.
15. Reload the IV set.
16. Close the Pump door.
17. Open the roller clamp.

18. Press RUN to resume infusion.

    The Check Flow screen appears.

19. Press the **yes** soft key to proceed to the Infusion Running screen.
20. Press **RUN/STOP** to stop the infusion.

    NOTE: In the event of a test failure, confirm failure by repeating the test with a new (unused) IV set.

21. Record the findings on the Preventive Maintenance Check Sheet.
22. If performing additional tests, ensure to re-prime the IV set to remove any remaining air in line.

Battery Capacity Test

Perform the Battery Capacity Test if a problem is suspected with the Pump's Battery Module. For instance, if the charge does not last as long as it should.

NOTE: Prior to starting the test, charge a Standard Battery for a minimum of 12 hours. Charge a Wireless Battery Module for a minimum of 16 hours.

To test the battery capacity:

1. Plug the AC Power Adaptor into a working wall outlet and verify green LED is lit while plugged in.
2. Adjust an IV test set in a loop configuration, so as to circulate fluid around the loop.
3. Press **ON/OFF** to power on the Pump
4. Load the IV set into the Pump following the display prompts. Verify that the IV set is properly loaded.

   NOTE: If the IV set is not properly loaded, the test results will be invalid.

5. Press the **options menu** soft key.
6. Select **User Options** and press **OK**.
7. Select **Display Settings** and press **OK**.
8. Select **Display Adjust** and press **OK**.
9. Set the Backlight Level to **10** and press **OK**.
10. Press **exit** twice to return to the Options screen.
11. Select the **Biomed Options** and enter the first level Biomed password.
12. Select **Pump Testing** and press **OK**.
13. Select **Battery Test** and press **OK**.
14. Select **Battery Life Test** and press **OK**.

15. When the “Load tube into pump and push OK to continue” confirmation screen appears, press **OK**.
16. Enter or verify **125 mL/hr** for Rate and press **OK**.
17. Turn Low batt (battery) alarm **off** and press **OK**.
18. Turn Constant alarm **off** and press **OK**.
19. When “Done” is displayed, press **OK**.
20. If necessary, unplug the Pump’s AC Power Adaptor.
21. Ensure the current battery level indicates a fully charged battery (between 8.0V and 8.3V). If battery is fully charged, press **OK**.

    The Pump will run until the battery is depleted and will then power off.
22. After the battery is depleted, plug the Pump’s AC Power Adaptor into a powered wall receptacle or install a fully charged battery.

    When the Pump is powered, “Start to dead” and “Low to dead” will be displayed.

Pass criteria for a used battery

Standard Battery Module:

- ≥6 hours from “Start to dead”
- ≥31 minutes from “Low to dead”

Wireless Battery Module (WBM):

- ≥3 hours from “Start to dead”
- ≥31 minutes from “Low to dead”

Pass criteria after installation of a new battery (less than 30 days old)

Standard Battery Module:

- ≥8 hours from “Start to dead”
- ≥31 minutes from “Low to dead”

WBM:

- ≥4 hours from “Start to dead”
- ≥31 minutes from “Low to dead”

If the battery capacity is less than the pass criteria, the battery is reaching end of life. See your Service Manual.

Preventive Maintenance Check Sheet

When using the Annual Preventive Maintenance Check Sheet:

- Enter the Hospital/Facility name in the space provided.
- Enter the Biomed name and date of the test.
- Record the findings on the Preventive Maintenance Check Sheet.
- Retain the completed Preventive Maintenance Check Sheet for your records.
- Return any Pump that fails any inspection, test, or performance evaluation.

Hospital/Facility: _____

Biomed Name:_____Date:_____

Pump Identification

Serial Number:	(Pump):	(Label):
Software Version:		N/A
Active Drug Library:	(Pump):	(Facility):
Drug Library Date:	(Pump):	(Facility):

Pump Inspection

Inspection	Pass	Fail
1. Visual Inspection - Pump Inspect the Pump for visual signs of damage and damage to all exterior components such as dents, cracks, cuts, heat damage or fluid intrusion.		
● Pump Casing		
● Pump Display		
● Keypad		
● Keyhole		
● Pump Door		
● Power Connector on back of rear case		
● IV Set Tube Channel		
● Verify legibility of all labels. Replace labels as necessary.		
2. Visual Inspection - AC Power Adaptor Inspect the AC Power Adaptor for visual signs of damage and damage such as cracks, bent prongs, cuts, exposed wires or dents.		
● AC Power Adaptor Module		
● AC Power Adaptor Cord		
● AC Power Adaptor Cord Retainer		
● AC Power Adaptor Module LED		
● Verify legibility of all labels. Replace labels as necessary.		
3. Network Configuration - Wireless Battery Module Verify that the network configuration file is installed and that there is connectivity (green Icon). If no network configuration file is installed, see “Wireless Networking” in Service Manual.		

Preventive Maintenance Tests

Tests Performed	Pass	Fail
1. Keypad Test Perform the keypad test for proper key operation. Pass criteria: ● All keys work as intended		
2. Memory Test Pass criteria: ● Rate and VTBI parameters were saved. (Rate = 100 mL/hr VTBI = 50 mL)		
3. Downstream (Distal) Occlusion Sensor Test Test Results: _____ (check one: ___ kPa ___psi) Pass criteria: ● All steps completed successfully. ● Pump displays a DOWNSTREAM OCCLUSION alarm at a pressure within the 89 kPa ±41 kPa (13 psi ±6) psi occlusion trip pressure setting. ● Pump automatically restarts when occlusion is removed. (Rate =100 mL VTBI = 50 mL) (48 kPa to 131 kPa) (7 psi to 19 psi)		
4. Upstream (Proximal) Occlusion Sensor Test Pass criteria: ● All steps completed successfully. ● Pump goes into UPSTREAM OCCLUSION alarm prior to the “infusion complete” message. (Rate = 100 mL/hr VTBI = 13.3 mL) (approximately 8 min)		
5. Flow Rate Accuracy Test Check the test performed: _____ Gravimetric Test_____ Volumetric Test **Volumetric** Volumetric: _____ mL Pass criteria: ● Collected fluid of 20.0 mL ±5% (19.0 - 21.0 mL) (Rate = 40 mL/hr, VTBI = 20 mL) (Time = 30 min) **Gravimetric** Gravimetric: _____ g Pass criteria: ● Collected fluid of 20.0 g ±5% (19.0 - 21.0 g) (Rate = 40 mL/hr, VTBI = 20 mL) (Time = 30 min)		

Tests Performed	Pass	Fail
6. Air Detection Test Pass criteria: ● All steps completed successfully. ● Pump goes into Air in Line alarm. (Rate = 100 mL/hr VTBI = 50 mL)		
7. Battery Capacity Test Perform the Battery Capacity Test to determine the storage capacity of the battery. *NOTE:* Test time approximately 9 hours. ● Start Time Date: _____ ● Time “Start to dead” = _____Hrs. _____Min. ● End Time Date: _____ Pass criteria Standard Battery ■ Used: ≥6 hours from “Start to dead” ■ New: ≥8 hours from “Start to dead” Wireless Battery ■ Used: ≥3 hours from “Start to dead” ■ New: ≥4 hours from “Start to dead”		
● Start Time Date: _____ ● Time “Low to dead” = _____Hrs. _____Min. ● End Time Date: _____ Pass criteria Standard Battery ■ Used: ≥31 minutes from “Low to dead” ■ New: ≥31 minutes from “Low to dead” Wireless Battery ■ Used: ≥31 minutes from “Low to dead” ■ New: ≥31 minutes from “Low to dead”		